In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: September 10, 2020

For Publication

KRISTIE ROBY	*	No. 15-125V
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Hepatitis B Vaccine; Connective tissue disease; Scleroderma
Respondent.	*	

Richard Gage, Richard Gage, PC, Cheyenne, WY, for Petitioner.
Lynn Schlie, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

On February 9, 2015, Kristie Roby ("Petitioner") filed a petition for compensation, pursuant to the National Vaccine Injury Compensation Program ("Program" or "Act"). Pet. at 1, ECF No. 1; 42 U.S.C. § 300aa-10 to -34 (2012). Petitioner alleged that she received a combined vaccination for hepatitis A and hepatitis B on June 27, 2013 that caused her to suffer pain, fatigue, and weakness. Pet. at 1. Petitioner filed an amended petition on April 22, 2016, alleging that the vaccination "triggered scleroderma with accompanying symptoms of pain, fatigue, and weakness." Am. Pet. at 2, ECF No. 42. Petitioner revised her claim again in her post-hearing memorandum, alleging that she developed undifferentiated connective tissue disease and sine scleroderma[2] as a result of the hepatitis B component of the vaccine. Pet'r's Post-Hr'g Br. at 1–2, ECF No. 87.

[1] This Decision shall be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted Decision. If, upon review, I find that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] Scleroderma in general is the "chronic hardening and thickening of the skin." *Scleroderma*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=45002&searchterm=scleroderma (last visited Aug. 17, 2020). Sine scleroderma occurs in a small number of patients who experience "the presence of visceral involvement occurring in the absence of skin manifestations." *See* Pet'r's Ex. 34 at 2: E. Kucharz, M. Kopeć-Mędrek, *Systemic sclerosis sine scleroderma,* ADV. CLIN. EXP. MED. (2017)

After carefully analyzing and weighing all the evidence and testimony presented in this case in accordance with the applicable legal standards, I find that Petitioner has not met her legal burden. Petitioner has failed to provide preponderant evidence that the hepatitis vaccination she received on June 27, 2013 caused her to develop scleroderma. Accordingly, Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed her claim on February 9, 2015. She initially alleged she suffered pain, fatigue, and weakness as the result of receiving a combination hepatitis A and B vaccination on June 27, 2013. Pet. at 1. The case was assigned to Special Master Lisa Hamilton-Fieldman and, over the next six months, Petitioner filed exhibits in support of her claim. ECF Nos. 9, 10, 17, 20, 23.

On September 30, 2015, Respondent contested entitlement in his Rule 4(c) report, noting that Petitioner had not alleged a specific injury. ECF No. 27. At a status conference on October 14, 2015, Petitioner indicated that the alleged injury would likely be scleroderma. ECF No. 30. She filed additional medical records on March 4, 2016, and an amended petition on April 22, 2016, claiming the vaccination "triggered" her scleroderma. ECF Nos. 38, 42.

Petitioner submitted an expert report from Dr. Vera Byers on August 31, 2016, who opined that the vaccination caused or substantially contributed to Petitioner's development of an autoimmune disorder. ECF No. 46-1. On November 28, 2016, Respondent filed an expert report from Dr. Chester Oddis who disagreed that Petitioner even had an autoimmune disorder. ECF No. 50-1.

On December 15, 2016, Special Master Hamilton-Fieldman held a status conference to address the uncertainty of Petitioner's diagnosis and resulting failure of the experts' ability to reach the issue of causation. ECF No. 51. Special Master Hamilton-Fieldman ordered Petitioner to file updated records and a supplemental responsive expert report from Dr. Byers. *Id*.

The case was reassigned to me on January 11, 2017. ECF No. 53. Over the following months, Petitioner submitted updated medical records and a supplemental expert report. ECF Nos. 55, 61. Respondent also submitted a supplemental responsive expert report. ECF No. 63. On August 3, 2017, the parties contacted me to request an entitlement hearing, which was then set for March 14, 2019. ECF No. 66.

In preparation for the entitlement hearing, the parties each filed a pre-hearing memorandum and supplemental exhibits including records, medical literature, and reports. ECF Nos. 68, 71–75, 77–79, 81. I held an entitlement hearing on March 14, 2019, and heard testimony from Petitioner, Dr. Byers, and Dr. Oddis. Petitioner filed a post-hearing brief in which she further refined her allegations, claiming she developed undifferentiated connective tissue disease and scleroderma sine scleroderma, specifically from the hepatitis B component of the combined vaccination. ECF No. 87. Respondent filed a post-hearing memorandum with demonstrative charts from the hearing. ECF Nos. 90, 93. This matter is now ripe for adjudication.

26(5):875-880.

II. Factual Background

A. Medical Records

Petitioner was 40 years old and working as a nurse in a jail when she received a combined vaccine for hepatitis A and B[3] on June 27, 2013. Pet'r's Ex. 10. In the three months prior to vaccination, she saw her primary care physician ("PCP"), Rolf Lyon, M.D., twice: first for moodiness on April 5, 2013, then for pain in her left calf on June 3, 2013. Pet'r's Ex. 1 at 1–5. Dr. Lyon's records are sparse but indicate Petitioner complained of crying and excessive anger in April. *Id.* In response, Dr. Lyon checked her hormones, increased her Effexor,[4] and assessed her with vasomotor instability[5] and Raynaud's.[6] *Id*. Then, in June, in response to her complaints of left calf pain, he noted the Raynaud's again, and included post-traumatic stress disorder ("PTSD") and anxiety in his assessment. Dr. Lyon recommended over-the-counter niacin and a psychiatric referral. *Id*. In addition to the Effexor, Petitioner's medication list at this time included Procardia,[7] Alprazolam,[8] and Topamax.[9] *Id*. Before seeing Dr. Lyon, Petitioner was treated by Elaine Wood,

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[3] Twinrix vaccine – "a combination preparation of hepatitis A vaccine inactivated and hepatitis B vaccine (recombinant)." *Twinrix*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=51545&searchterm=Twinrix (last visited Aug. 17, 2020).

[4] Effexor is "used as an antidepressant and antianxiety agent." *Venlafaxine hydrochloride*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=52779 (last visited Aug. 17, 2020); *Effexor*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=15636&searchterm=Effexor (Aug. 17, 2020) ("trademark for preparations of venlafaxine hydrochloride").

[5] Vasomotor instability is not a readily definable term.

[6] Raynaud's phenomenon is "intermittent bilateral ischemia of the fingers, toes, and sometimes ears and nose, with severe pallor and often paresthesia and pain, usually brought on by cold or emotional stimuli and relieved by heat; it is usually due to an underlying disease or anatomic abnormality." *Raynaud Phenomenon*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=97633&searchterm=Raynaud+phenomenon (last visited Aug. 17, 2020).

[7] Procardia is a "a calcium channel blocking agent used as a coronary vasodilator in the treatment of coronary insufficiency and stable angina pectoris, and as an antihypertensive." *Nifedipine*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=34003 (last visited Aug. 17, 2020); *Procardia*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=41007&searchterm=Procardia (Aug. 17, 2020) ("trademark for preparations of nifedipine").

[8] Alprazolam is "a short-acting benzodiazepine used as an antianxiety agent in the treatment of anxiety disorders and panic disorders and for short-term relief of anxiety symptoms." *Alprazolam*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=1937&searchterm=alprazolam (last visited Aug. 17, 2020).

[9] Topamax is "a substituted monosaccharide used as an anticonvulsant in the treatment of partial seizures." *Topiramate*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=50310 (last visited Aug. 17, 2020); *Topamax*, *Dorland's Medical Dictionary Online*, *Topiramate*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=50298&searchterm=Topamax (Aug. 17, 2020) ("trademark for a preparation of topiramate.").

D.O., who provided refills of Petitioner's Xanax and Effexor prescriptions from 2010 through 2012. *See generally* Pet'r's Ex. 18.

On July 1, 2013, four days after vaccination, Petitioner presented to John Popp, M.D., complaining of painful joints, fatigue, and sores in her mouth. Pet'r's Ex. 8 at 1. Dr. Popp's nurse noted Petitioner had a "one-week history of being very fatigued and all of her joints hurting." *Id*. Petitioner rated the pain as moderate to severe and worse in the morning. *Id*. Petitioner described sores in her mouth, stating that she gets them "fairly regularly." *Id.* None were noted to be present at the visit. *Id*. The physical exam was normal, and Dr. Popp diagnosed Petitioner with fatigue and polyarthritis. Pet'r's Ex. 8 at 3. He ordered lab work and x-rays of her hands then prescribed a course of Prednisone.[10] *Id*. The lab work was within normal limits, and the x-rays were negative for chronic arthritis. Pet'r's Ex. 3 at 1–4, Ex. 2 at 5.

Petitioner returned to Dr. Lyon on July 4, 2013 complaining of "trouble breathing, chest pain, chills, and joint aching." Pet'r's Ex. 1 at 6. Dr. Lyon assessed her with Reiter's syndrome,[11] administered a Rocephin injection,[12] and ordered further tests, including an echocardiogram. *Id*. at 8–10. The results of all tests were normal. *Id*.

Petitioner next sought treatment on July 17, 2013 from rheumatologist, M. Sami Mughni, M.D., at the Florida Arthritis and Osteoporosis Center. Pet'r's Ex. 3 at 9–12. Dr. Mughni noted that Petitioner had a longstanding history of PTSD and three weeks of "increasing pain and stiffness involving multiple joints and muscle groups." *Id*. He indicated that her condition did not respond to high-dose steroids and that Petitioner had received a "hepatitis vaccination [four] days before acute exacerbation of symptoms." *Id*. Dr. Mughni wrote the following in the review of systems: "Constipation. Acid reflux. Shortness of breath. Headaches. Dizzy spells. Low-grade fever. Some sensitivity. Sinus infections. Raynaud's." *Id*. The examination was normal with no synovitis,[13] negative serologies or x-rays, and Dr. Mughni concluded that Petitioner had

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[10] Prednisone is "a synthetic glucocorticoid derived from cortisone, administered orally as an anti-inflammatory and immunosuppressant in a wide variety of disorders." *Prednisone*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=40742&searchterm=prednisone (last visited Aug. 17, 2020).

[11] Reiter's syndrome is "the triad of acute aseptic arthritis, nongonococcal urethritis, and conjunctivitis; there may also be mucocutaneous manifestations such as keratoderma blennorrhagicum, circinate balanitis, and stomatitis." *Reiter syndrome*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=111277 (last visited Aug. 17, 2020).

[12] Rocephin is "a semisynthetic, β-lactamase–resistant, broad-spectrum, third-generation cephalosporin effective against a wide range of gram-positive and gram-negative bacteria." *Ceftriaxone sodium*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=8471 (last visited Aug. 17, 2020); *Rocephin*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=44026&searchterm=Rocephin (Aug. 17, 2020) ("trademark for a preparation of ceftriaxone.").

[13] Synovitis is the "inflammation of a synovial membrane; it is usually painful, particularly on motion, and is characterized by a fluctuating swelling due to effusion within a synovial sac. Some types are named for accompanying tissue changes, such as *fibrinous, hyperplastic,* or *lipomatous synovitis;* others are named for accompanying disease processes or complications, such as *gonorrheal, metritic, puerperal, rheumatic, scarlatinal, syphilitic,* or *tuberculous synovitis.*" *Synovitis*, *Dorland's Medical Dictionary*

fibromyalgia and chronic fatigue syndrome. *Id*. He noted, however, that these diagnoses did not explain the "acute exacerbation recently associated with joint swelling." *Id*. He recommended she continue Seroquel for PTSD, add niacin for Raynaud's, and follow-up in two months. *Id*. at 11. Petitioner returned to Dr. Mughni one week later still complaining of pain and stiffness. Pet'r's Ex. 3 at 12–13. He confirmed the previous diagnoses and added Effexor plus hydrocodone for pain control. *Id*.

Dr. Mughni referred Petitioner to neurologist, Qahtan Adbul Fattah, M.D., at The Headache and Neurology Clinic for an examination on August 1, 2013. Pet'r's Ex. 2 at 8–10. Dr. Fattah indicated Petitioner was "worried about having [multiple sclerosis]." *Id*. He wrote:

> [Petitioner] received vaccine for hepatitis A and B at work as she is an RN. [Four] days later she started having muscle pain and swollen joints. Steroids and antibiotics did not help. She has been falling and feeling weak all over. She is tired and [has] no energy. Her hands are also weak[,] and she finds it hard to hold on things. Her chronic finger numbness has also gotten worse.

Id. He performed a neurological exam which was normal and commented that "her symptoms are likely a reaction to vaccination." *Id*. Dr. Fattah prescribed Gabapentin[14] and ordered labs and a spinal MRI. *Id*. Petitioner returned on September 9, 2013, still reporting problems with walking and muscle pain. *Id*. at 14. Dr. Fattah diagnosed her with "hyper-reflexia with mute toes"[15] and myalgia and further recommended an MRI of the head. The MRI occurred on December 13, 2013 and revealed she might have a pituitary microadenoma,[16] but was otherwise normal. *Id*. at 15–16.

Petitioner followed up with Dr. Mughni on October 3, 2013, who described Petitioner as having fibromyalgia with poor response to intervention. Pet'r's Ex. 3 at 19. Her serologies were

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Online, https://www.dorlandsonline.com/dorland/definition?id=48576&searchterm=synovitis (last visited Aug. 19, 2020).

[14] Gabapentin is "an anticonvulsant that is a structural analogue of γ-aminobutyric acid (GABA), used as adjunctive therapy in the treatment of partial seizures and the management of postherpetic neuralgia." *Gabapentin*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=19523&searchterm=gabapentin (last visited Aug. 17, 2020).

[15] Hyperreflexia is "dysreflexia characterized by exaggeration of reflexes." *Hyperreflexia*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=23992&searchterm=hyperreflexia (last visited Aug. 17, 2020). A definition for mute toes is not readily available.

[16] Microadenoma is "specifically, a pituitary adenoma less than 10 mm in diameter and not visible by usual radiographic techniques; most endocrine-active adenomas are this size and are detected because of their hormone activities." *Microadenoma*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=31164&searchterm=microadenoma (last visited Aug. 19, 2020).

normal with negative ANA,[17] negative rheumatoid factor,[18] and normal ESR.[19] *Id*. He confirmed he did not see clinical evidence of SLE[20] or rheumatoid arthritis and he thought her symptoms were consistent with fibromyalgia and osteoarthritis. *Id*. He continued the hydrocodone as needed, plus Effexor, Seroquel, and Xanax for depression and anxiety. *Id*.

During the first half of 2014, Petitioner visited numerous specialists for clarification of her diagnosis and treatment of her symptoms. First, she went to neurosurgeon, Steven Bailey, M.D., on January 31, 2014, who evaluated her for neck pain and upper extremity numbness. Pet'r's Ex. 4 at 1–3. He ruled out Petitioner's need for neck surgery but recommended EMG and nerve conduction studies. *Id*. The upper extremity EMG performed on February 6, 2014 revealed bilateral carpal tunnel syndrome and diffuse sensory delays in both hands, with an underlying mild sensory neuropathy of an unknown origin. *Id*. at 9. The EMG of the lower extremities was normal. *Id*. at 11. On March 14, 2014, Dr. Bailey referred Petitioner for a carpal tunnel release and suggested she follow-up with a rheumatologist and an endocrinologist. *Id*. at 16–18.

Neurosurgeon, Steven Reid, M.D., evaluated Petitioner for bilateral hand weakness on March 26, 2014, and noted that Petitioner thought she had a condition called macrophagic myofasciitis.[21] Pet'r's Ex. 7 at 1. Petitioner wanted a deltoid muscle biopsy to confirm this

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[17] ANA is an abbreviation for antinuclear antibodies—which are "antibodies directed against nuclear antigens; ones against a variety of different antigens are almost invariably found in systemic lupus erythematosus and are frequently found in rheumatoid arthritis, scleroderma (systemic sclerosis), Sjögren syndrome, and mixed connective tissue disease." *Antinuclear antibodies*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=56804 (last visited Aug. 17, 2020).

[18] Rheumatoid factor is "antibodies directed against antigenic determinants, i.e., Gm, in the Fc region of the IgG class of immunoglobulins; these are found in the serum of about 80 percent of persons with classical or definite rheumatoid arthritis but only about 20 percent of those with juvenile rheumatoid arthritis." *Rheumatoid factor*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=74591&searchterm=rheumatoid+factor (last visited Aug. 17, 2020).

[19] ESR (erythrocyte sedimentation rate) is "the rate at which erythrocytes precipitate out from a well-mixed specimen of venous blood, measured by the distance the top of the column of erythrocytes falls in a given time interval under specified conditions; an increase in rate is usually due to elevated levels of plasma proteins, especially fibrinogen and immunoglobulins, which decrease the zeta potential on erythrocytes by dielectric shielding and thus promote rouleau formation. It is increased in monoclonal gammopathy, hypergammaglobulinemia due to inflammatory disease, hyperfibrinogenemia, active inflammatory disease, and anemia." *Erythrocyte sedimentation rate*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=102146&searchterm=erythrocyte+sedimentation+rate (last visited Aug. 17, 2020).

[20] SLE is an abbreviation for systemic lupus erythematosus, "a chronic, inflammatory, often febrile multisystemic disorder of connective tissue that proceeds through remissions and relapses; it may be either acute or insidious in onset and is characterized principally by involvement of the skin *(cutaneous l. erythematosus),* joints, kidneys, and serosal membranes." *Systemic lupus erythematosus*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=87476 (last visited Aug. 17, 2020).

[21] Macrophagic myofasciitis is detected in patients with diffuse arthromyalgias and fatigue. It is characterized by muscle infiltration by granular periodic acid-Schiff's reagent-positive macrophages and lymphocytes. *See D'Angiolini v. Sec'y of Health & Human Servs.,* No. 99-578V, 2014 WL 1678145 (Fed.

diagnosis. *Id.* Dr. Reid performed bilateral deltoid muscle biopsies and a right median nerve neuroplasty[22] on June 12, 2014. *Id*. at 14–15. The neuroplasty was successful in relieving some right-hand symptoms, but the muscle biopsies did not confirm pathology. *Id*. at 16.

Petitioner saw endocrinologist, Sreevidya Subbarayan, M.D., to follow up on the potential pituitary microadenoma revealed by the MRI performed by Dr. Fattah. Pet'r's Ex. 5 at 3, 8–12. Petitioner indicated she received the combined hepatitis A and B vaccination and developed painful swelling in her joints three days later. *Id*. Dr. Subbarayan wrote that "patient states that [she] researched into her issue and found that there is a rare syndrome caused by aluminum in the vaccine." *Id*. at 8. Dr. Subbarayan advised Petitioner that she might have a pituitary microadenoma, but it was unlikely to be the cause of her various symptoms since her hormonal profile was completely normal. *Id*.

Petitioner consulted with a second rheumatologist, Miguel Rodriguez, M.D., at the Southeastern Arthritis Center, in March and April of 2014. Pet'r's Ex. 6 at 7–8. Dr. Rodriguez sent Petitioner for a series of joint x-rays, lab work, and a CT of the chest. *Id*. at 2–11. Dr. Rodriguez noted a positive SCL-70[23] (which would suggest scleroderma), a negative ANA, and an abnormal CT of the chest, but he advised her that the diagnosis was unclear. *Id*. at 14–15. He recommended she go to a specialty center such as Cleveland Clinic or Johns Hopkins for further evaluation and treatment. *Id*. at 15.

The day after, Dr. Rodriguez advised Petitioner of the abnormal serology findings. Petitioner returned to her first rheumatologist, Dr. Mughni, on April 10, 2014. Pet'r's Ex. 3 at 29. He wrote that she had a positive SCL-70 and Raynaud's phenomenon but no objective evidence of inflammation or other skin changes suggestive of scleroderma. *Id.* at 30. Dr. Mughni suspected most of Petitioner's symptoms were due to fibromyalgia and chronic fatigue syndrome. He explained to Petitioner that the physical examination did not support the diagnosis of scleroderma, although she may progress to it in the future. *Id*. at 30–31. He recommended evaluation by another rheumatologist, because he was unable to control her symptoms. *Id*.

Cl. Mar. 27, 2014), *aff'd,* 122 Fed. Cl. 86 (2015), *aff'd,* 645 F. App'x 1002 (Fed. Cir. 2016) (citing R.K. Gherardi et al., *Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived [aluminum] hydroxide in muscle,* 124 BRAIN 1821, 1826 (2001)). Macrophages are "any of the many forms of mononuclear phagocytes found in tissues. They arise from hematopoietic stem cells in the bone marrow, which develop according to the stages of the monocytic series until they are monocytes; these then enter the blood, circulate for about 40 hours, and subsequently enter tissues, where they increase in size, phagocytic activity, and lysosomal enzyme content to become macrophages." *Macrophage*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=29296&searchterm=macrophage (last visited Aug. 18, 2020).

[22] Neuroplasty is "plastic surgery of a nerve." *Neuroplasty*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=33823&searchterm=neuroplasty (last visited Aug. 17, 2020).

[23] According to Mayo Clinical Laboratories, testing for SCL-70 antibodies is useful for "[e]valuating patients with signs and symptoms of scleroderma and other connective tissue diseases in whom the test for antinuclear antibodies is positive." *Test ID: SCL-70*, MAYO CLINIC LABORATORIES, https://www.mayocliniclabs.com/test-catalog/Overview/80178 (last visited Aug. 17, 2020).

On May 14, 2014, Petitioner saw rheumatologist, John Donohue, M.D., of the Cleveland Clinic for a consultation. Pet'r's Ex. 16 at 1–7. He examined Petitioner and described her as having diffuse musculoskeletal pain without frank synovitis. *Id*. at 5. Although she had an elevated SCL-70 antibody, he noted she had no skin manifestations of scleroderma other than mild Raynaud's phenomenon. *Id*. He advised Petitioner that it was possible she had early scleroderma, but there was no specific therapy given her lack of findings. *Id*. He determined her musculoskeletal discomfort was likely myofascial pain and wrote that "there [was] no objective muscle weakness and her muscle enzymes and inflammatory markers [were] normal." *Id*. He suggested formal neuropsychiatric testing to determine whether her memory issues had organic versus functional origin. *Id*. A pulmonologist at the clinic also reviewed the abnormal chest CT; he determined there was no evidence of scleroderma lung and suggested the CT be repeated in six months. *Id*. at 8–11.

Other than a pain management appointment in July, Petitioner did not seek treatment for the rest of 2014. Pet'r's Ex. 9 at 1. Petitioner resumed treatment in 2015, starting with a behavioral health consult on January 20, 2015. Pet'r's Ex. 15 at 1–4. She was diagnosed with PTSD, chronic and "major depressive disorder, recurrent, severe, without psychotic features[,]" and her psychiatric medications were adjusted. *Id*. at 3–4.

Rheumatologist, Yih Lin, M.D., treated Petitioner during 2015 and 2016. Pet'r's Ex. 14 at 1–4, Ex. 22 at 17–19, Ex. 19 at 3–5, ECF Nos. 45, 47. Dr. Lin noted on March 10, 2015 that Petitioner described her symptoms starting after a hepatitis vaccination in June of 2013. Pet'r's Ex. 14 at 1–4. Dr. Lin referenced Petitioner's positive SCL-70 and Raynaud's and concluded she likely had undifferentiated connective tissue disease[24] with possible systemic sclerosis[25] (although Dr. Lin indicated she did not satisfy the criteria at the time). *Id*. Dr. Lin suggested a trial of

[24] Undifferentiated connective tissue disease ("UCTD") is a concept "used to typify individuals who present with clinical and serologic features suggestive of a connective tissue disease ("CTD"), but who do not meet criteria for a definable CTD like systemic lupus, Sjögren's, scleroderma, or mixed connective tissue disease ("MCTD"), but yet may be at risk for developing significant disease over time." *L.A.M. v. Sec'y of Health & Human Servs.,* No. 11-852V, 2017 WL 897430 (Fed. Cl. Jan. 31, 2017). Mixed connective tissue disease is "a disorder combining features of scleroderma, myositis, systemic lupus erythematosus, and rheumatoid arthritis, and marked serologically by the presence of antibody against extractable nuclear antigen." *Mixed connective tissue disease*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=70607 (last visited Aug. 19, 2020).

[25] Systemic sclerosis (also known as systemic scleroderma) is "a systemic disorder of the connective tissue characterized by fibrosis with hardening and thickening of the skin, as well as abnormalities of both microvasculature (telangiectasias) and larger vessels (Raynaud phenomenon); there are also fibrotic degenerative changes in body organs such as the heart, lungs, kidneys, and gastrointestinal tract. It may be confined to the face and hands for long periods or may progress, spread diffusely, and become generalized. Called also *diffuse s.* and *systemic sclerosis.*" *Systemic scleroderma*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=105101 (last visited Aug. 17, 2020).

hydroxychloroquine[26] and a referral to a swallowing center for dysphagia.[27] *Id*. On January 8, 2016, Dr. Lin noted that Petitioner's disease had not improved; she had continuing dysphagia, joint pain and swelling, and shortness of breath. Pet'r's Ex. 22 at 17–19. Dr. Lin switched Petitioner from hydroxychloroquine to methotrexate[28] and recommended symptomatic care for the Raynaud's. *Id*. Petitioner followed up with Dr. Lin again on May 9, 2016, and he noted Petitioner's disease was stable, and her joint pains were better since starting methotrexate. Pet'r's Ex. 19 at 3–5.

In addition to Dr. Lin, Petitioner saw other specialists throughout 2015 and 2016 for evaluation of her varied symptoms. She saw a neurologist who assessed her with diffuse muscle weakness, pseudodementia,[29] and sensory polyneuropathy. Pet'r's Ex. 17 at 1-–5, Ex. 22 at 8–12. An ophthalmologist diagnosed her with dry eyes and prescribed eye drops. Pet'r's Ex. 14 at 9–16. A gastroenterologist assessed her with acid reflux, dysphagia, and altered bowel function and ordered further tests. Pet'r's Ex. 14 at 5–7. A high-resolution esophageal motility study showed frequent failed peristalsis, possibly indicating early scleroderma esophagus. Pet'r's Ex. 12 at 2. Next, Petitioner was referred to Joel Richter, M.D., a swallowing specialist, and she underwent a gastric emptying study with abnormal results. Pet'r's Ex. 22 at 1–7, 20–22. Dr. Richter assessed her with "scleroderma with diffuse GI involvement, including bad esophageal reflux with aperistalsis, gastroparesis, and colonic inertia with bad constipation." Pet'r's Ex. 22 at 21. Dr. Richter referred her to a surgeon who determined she was not a good candidate for operative intervention. *Id*. at 30–31.

Pulmonologist, Kimberly Cao, M.D., evaluated Petitioner on May 18, 2015, for complaints of shortness of breath and hoarseness, and referred her for a vocal cord evaluation. Pet'r's Ex. 17

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[26] Hydroxychloroquine is "a 4-aminoquinoline compound with antiprotozoal and anti-inflammatory properties, used for suppression and treatment of malaria, for suppression of lupus erythematosus, and as an anti-inflammatory disease-modifying antirheumatic drug in treatment of rheumatoid arthritis." *Hydroxychloroquine sulfate*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=23495&searchterm=hydroxychloroquine+sulfate (last visited Aug. 17, 2020).

[27] Dysphagia is "difficulty in swallowing." *Dysphagia*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=15265&searchterm=dysphagia (last visited Aug. 18, 2020).

[28] Methotrexate is "a folic acid antagonist that acts by inhibiting synthesis of DNA, RNA, thymidylate, and protein; used as an antineoplastic in treatment of a wide variety of malignancies, including acute lymphocytic, meningeal, and acute myelocytic leukemia; gestational choriocarcinoma; chorioadenoma destruens; hydatidiform mole; carcinoma of the breast, lung, and head and neck; non-Hodgkin lymphomas; mycosis fungoides; and osteosarcoma; administered orally. It is also used as an antipsoriatic and antiarthritic in the treatment of severe, recalcitrant, disabling psoriasis and severe rheumatoid and psoriatic arthritis." *Methotrexate*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=30930&searchterm=methotrexate (last visited Aug. 18, 2020).

[29] Pseudodementia is "a disorder resembling dementia but that is not due to organic brain disease and is potentially reversible by treatment; usually due to depression or other psychiatric disorder." *Pseudodementia*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=41668&searchterm=pseudodementia (last visited Aug. 18, 2020).

at 45–49. Although Petitioner was asymptomatic during assessment, her "complaints were determined to be consistent with a component of vocal cord dysfunction." *Id*. at 64. Repeated chest CTs showed Petitioner's lung nodules to be stable. Pet'r's Ex. 19 at 6. A right heart catheterization on June 26, 2015 was normal with no evidence of pulmonary hypertension. *Id*. at 16.

Throughout 2015 and 2016, Petitioner continued to experience body pain and she attended pain management appointments once or twice per month. *See generally* Pet'r's Ex 23. She was prescribed Percocet for pain and tizanidine, a muscle relaxer. Several referrals for physical therapy are noted in the record, but it is unclear if she went. Pet'r's Ex. 23 at 79, 120.

Petitioner relocated to Illinois in 2017 and began treatment with Eric Graham, M.D. *See generally* Pet'r's Ex. 26. Dr. Graham saw Petitioner for the first time on January 24, 2017 and wrote "[s]he is a 43 [year old] white female with a history of systemic scleroderma. [Petitioner] has multiple other issues that give her problems sometimes, including Raynaud's, DJD, PTSD, and GI problems including gastroparesis and constipation." Pet'r's Ex. 26 at 67–69. Over the next two years, Petitioner met with Dr. Graham once or twice per month for her symptoms. Occasionally, her visits related to scleroderma, but were frequently due to other complaints, such as respiratory infections or accidental injuries. See e.g. Pet'r's Ex. 26 at 55–57, 49, 31–34, 16–19.

Dr. Graham referred Petitioner to Monique Hinchcliff, M.D., of the Northwestern Scleroderma Clinic. Dr. Hinchcliff saw Petitioner for the first time on March 20, 2017. Pet'r's Ex. 26 at 155. Dr. Hinchcliff examined Petitioner, noting 2008 as the year of Raynaud's onset and 2015 as the year of onset of her joint pain (the first non-Raynaud's symptom). *Id*. at 156. Although Dr. Hinchcliff did not assess whether Petitioner met the 2013 ACR/EULAR[30] criteria for scleroderma, she wrote her impression as "undifferentiated CTD versus SSC sine scleroderma."[31] *Id*. at 155–160. Petitioner saw Dr. Hinchcliff again on April 14, 2017. Pet'r's Ex. 24 at 1–5. Dr. Hinchcliff wrote that Petitioner had a hepatitis vaccine in 2013 then developed flu-like symptoms, such as joint swelling and pain. *Id.* Petitioner complained of weakness, muscle and joint pain, dry eyes, and shortness of breath. *Id*. Dr. Hinchcliff again noted her impression as "undifferentiated CTD versus SSC sine scleroderma," with "GI involvement with gastroparesis, constipation[,] and difficulty swallowing." *Id*. Dr. Hinchcliff made recommendations regarding laxatives and exercise and referred Petitioner to a gastrointestinal specialist and a dietician. *Id.*

[30] ACR/EULAR criteria—established by the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR)—are the classification criteria for systemic sclerosis (SSc). In developing the criteria, the "objective was to develop a set of criteria that would enable identification of individuals with SSc for inclusion in clinical studies, being more sensitive and specific than previous criteria." Frank van den Hoogen et al., *2013 Classification Criteria for Systemic Sclerosis*, 65:11 Arthritis & Rheumatism 2737, 2737–39 (November 2013) ("This criteria has been approved by the [ACR] Board of Directors and the [EULAR] Executive Committee.").

[31] Dr. Hinchcliff indicated her impression of Petitioner's condition as "undifferentiated CTD versus SSC sine scleroderma." I attribute Dr. Hinchcliff's use of the word "versus" to account for the overlap in Petitioner's symptoms and to show that she suffers from one or both of these conditions simultaneously. Therefore, throughout the Decision, I refer to Petitioner's diagnosis interchangeably between "undifferentiated CTD versus SSC sine scleroderma" and "undifferentiated CTD and SSC sine scleroderma."

Petitioner returned to the Northwestern Scleroderma Clinic on January 18, 2019, for an evaluation by Chase Correia, M.D. Pet'r's Ex. 27 at 2–10. Dr. Correia wrote that Petitioner has joint pains and Raynaud's, mostly in her feet. *Id*. at 2. Dr. Correia ordered laboratory tests and made a series of recommendations including following up with a specialist for her gastrointestinal symptoms. *Id*. at 9. The lab tests revealed a positive SCL-70 and Petitioner's first positive ANA, speckled. Pet'r's Ex. 31 at 9. Darren Brenner, M.D., evaluated Petitioner on February 6, 2019 and suggested further GI tests in order to determine future recommendations. Pet'r's Ex. 33 at 4.

B. Fact Testimony

Petitioner testified at the entitlement hearing that she spent most of her life in Florida and became a licensed practical nurse in 2005. Tr. 10:7–21. She worked as a nurse within a jail and, due to the risks of working within the facility, received a hepatitis vaccination on June 27, 2013. Tr. 11:8–21. She recalled receiving at least three hepatitis B vaccinations previously, but this vaccine included hepatitis A, which she had not received before. Tr. 12:25–13:9.

Although Petitioner stated she felt fine on the day of the vaccination, she described feeling achy and unwell on the following Saturday. Tr. 12:14–15, 13:25. By Sunday morning, she noticed her hands and feet were puffy, and she hurt all over like she had the flu. Tr. 14:1–3, 15:1–3. Her husband took her to the Allen Ridge walk-in clinic, because she could not drive herself. Tr. 16:4–6. Dr. Popp told her he thought she had acute rheumatoid arthritis. Tr. 16:14–25. She testified that Dr. Popp knew she was in bad shape, because the swelling was visible, and he told her to see her primary care doctor. Tr. 17:7–16.

As an aside, Petitioner mentioned that prior to vaccination (she did not remember the date), Dr. Lyon (her PCP) told her she had Raynaud's. Tr. 18:1–11. She recounted that he noticed her feet were gray, and she agreed that "they turn gray sometimes and they are cold." Tr. 18:5–11.

Petitioner testified that Dr. Popp's records incorrectly state that she had been having symptoms for a week, and she had a strong family history of rheumatoid arthritis. Tr. 19:8–19. Petitioner clarified that only her grandmother on her mother's side had rheumatoid arthritis, and she would not have gone to work or received the vaccine if she had been symptomatic for a week. Tr. 19:15–20:8. She was unsure who made the incorrect notes at Dr. Popp's office. Tr. 19:20–20:4.

Next, Petitioner recounted an appointment with Dr. Lyon and stated that he thought she had an STD or Reiter's syndrome. Tr. 21:6–11. Dr. Lyon referred her to Dr. Mughni, a rheumatologist, who thought she had fibromyalgia and chronic fatigue syndrome. Tr. 21:14–22:21. As a nurse, she heard doctors talk about fibromyalgia. Tr. 22:22–23. Petitioner understood that it is a "bucket disease" that is diagnosed when doctors do not know what is wrong with you. Tr. 22:22–24. She thought Dr. Mughni would treat her symptoms even though he did not know what was wrong with her, and she hoped it would give her some relief. Tr. 22:24–23:2.

By August 1, 2013, Petitioner had tried steroids, which took the swelling down some and antibiotics, that did nothing. Tr. 28:2–15. She was still in pain and looking for an answer. Tr. 28:13–15. Her symptoms interfered with her job, but she had helpful coworkers. Tr. 29:1–25.

She ultimately had to quit her job when she had to use two hands to give a shot, which is not safe. Tr. 29:10–18. Her husband had to quit college and help at home. Tr. 29:5–9.

Petitioner questioned the language in her medical records from October of 2013, including the characterization of her illness as "chronic", when she had only been sick for a month. Tr. 26:12–14. Petitioner also questioned the description of a "long standing history of fibromyalgia." Tr. 30:17–25. In her history, Petitioner described some neck pain prior to the vaccination, because she was in a car accident when she was much younger and had ectopic pregnancies at ages 19 and 20. Tr. 31:9–25.

Petitioner testified that she had surgery on her right hand in early 2014 to address carpal tunnel syndrome. Tr. 33:8–12. She believes the surgeon, Dr. Reid, was the first doctor to mention an autoimmune disorder. Tr. 34:6–24. The surgery helped with the palm of her hand but did not help the swelling on her knuckles or her joints. Tr. 36:2–14.

Petitioner testified that about eight months post-vaccination, she underwent pain management that helped some, but the other symptoms persisted. Tr. 37:15–20. Dr. Rodriguez ran a panel of tests and told her the blood test was "highly positive for scleroderma." Tr. 37:9–38:3. She took the test again with the same result. Tr. 38:4–6. She had not previously heard of scleroderma. Tr. 38:18–21.

Petitioner was still working three days a week about a year after the vaccination with the assistance of her coworkers. Tr. 40:11–15. She was unable to tend to her hair and spent a lot of time going to doctors to find out what was wrong with her. Tr. 40:16–23. She stopped playing softball and gave up her hobbies. Tr. 41:5–6. She was on hydrocodone at that point and a pain management physician put her on Percocet and muscle relaxers. Tr. 41:15–19. Next, Petitioner tried a fentanyl patch, but it caused blurry vision. Tr. 41:20–24. Petitioner went back down to Percocet and has "pretty much stayed" on that, because she cannot handle stronger pain medication. Tr. 42:1–3.

Petitioner testified that a gastroenterologist, Dr. Richter, sent her for tests as part of a workup for scleroderma, because she was starting to choke when she ate. Tr. 42:13–43:22. Among other things, they shoved a tube down her nose and gave her water to drink while she was hooked up to machines. Tr. 43:15–25. Her test results indicated gastroparesis, and that her stomach was not churning to push the food out. Tr. 46:1–10. She temporarily stopped her pain medications several days before the test so they would not interfere with the results. Tr. 46:13–47:12.

Petitioner said she moved to Illinois to see Dr. Hinchcliff at the scleroderma clinic in Chicago, even though she loved living in Florida with her friends and family. Tr. 48:7–50:5. Dr. Hinchcliff and the Scleroderma Clinic improved her life by giving her the right treatments and the right medicines. Tr. 50:11–51:6. Petitioner is down to two Percocets and can walk without a walker. Tr. 51:7–8. She follows a recommended diet and uses a pool to improve function. Tr. 51:3–13.

Petitioner testified that her eyes feel very dry, describing the sensation as like "a cat's tongue licking across [her] eyes." Tr. 52:5–12. Her doctors have explained that it is part of the

scleroderma and she has prescription eye drops now. Tr. 52:6–14. She continues to have arthralgia pain, and she takes Percocet, Prednisone, and sometimes a Medrol dose pack. Tr. 53:2–9. Her gastric system "is basically a mess." Tr. 53:14. She has to carefully chew her food, or she will choke when she swallows. Tr. 53:14–17. Once she gets it down, the food just sits in her stomach and makes her miserable. Tr. 53:17–20. She also struggles with constipation. Tr. 54:4–15. Dr. Hinchcliff has told her the disease is progressive but not to be scared, because they have "modalities" and will do the best they can to care for her. Tr. 54:16–25.

Upon my questioning, Petitioner stated that the notations in her medical records of the fibromyalgia diagnosis and family history of rheumatoid arthritis were carried forward by her doctors unbeknownst to her. Tr. 58:2–5. She testified that she was not asked about it or asked to confirm it. Tr. 58:6–15. Petitioner also indicated that none of her doctors talked about being concerned about side effects of the drugs she was taking. Tr. 58:16–21.

III. Experts

A. Expert backgrounds

1. Petitioner's Expert, Vera Byers, M.D., Ph.D.

Dr. Byers submitted two expert reports and testified at the entitlement hearing. Pet'r's Exs. 20, 25; Tr. 61–142, 224–228. Dr. Byers received her Ph.D. in immunology from the University of California at Los Angeles in 1969 and her medical degree from the University of California at San Francisco in 1981. Pet'r's Ex. 21 at 1. She completed her residency at the University of California at San Francisco in 1984 and became board-certified in internal medicine the same year. *Id.*

Over the course of her career, Dr. Byers has held numerous academic and research positions, including serving as an adjunct professor of immunodermatology at the University of California at San Francisco from 1976–2008. *See id.* at 1–5. She currently serves as the President of Immunology, Inc., where her responsibilities include "[d]esign[ing] Phase I, II, [and] III clinical trials in autoimmune disease[s] and cancer[s]," and "present[ing] data at national and international scientific meetings and grand rounds." Pet'r's Ex. 21 at 1–2. Dr. Byers also has "[o]ver [three hundred] articles and abstracts published in peer[-]reviewed medical journals . . . ." *Id.* at 1. She currently "serves on the editorial board[s] of two leading cancer journals (Cancer Immunology and Immunotherapy), and [on National Institute of Health] review panels in tumor immunology." *Id.*

At the hearing, Petitioner offered Dr. Byers as an expert in clinical immunology with no objection from Respondent. Tr. 73:11–74:4. Petitioner also offered Dr. Byers as an expert in rheumatology, but Respondent objected. Tr. 77:21–22. Dr. Byers testified that her only expertise in the diagnosis of scleroderma was acquired during her residency for internal medicine and three-year fellowship where she saw rheumatologic conditions. Tr. 75:8–24. She noted no specialized rheumatology training. Tr. 75:19–24. Petitioner stated that Dr. Byers was qualified to read and interpret what treating doctors have done and confirmed that she would not make any separate rheumatological diagnoses as part of her testimony. Tr. 78:1–7.

2. Respondent's Expert, Chester Oddis, M.D.

Dr. Oddis submitted three expert reports and testified at the entitlement hearing. Resp't's Ex. A, C, E; Tr. 143–221. Dr. Oddis received his medical degree from Pennsylvania State University in 1980 where he subsequently performed his internship and residency in internal medicine. Resp't's Ex. B at 2. He is board-certified in both internal medicine and rheumatology. Resp't's Ex. A at 1. He is currently serving as the Director of the Myositis Center, where he sees patients three days a week and performs clinical research in rheumatology. *Id*.; Tr. 144. His primary clinical and research interests for the past 30 years include all features of the idiopathic inflammatory myopathies. Resp't's Ex. A at 2. Dr. Oddis has seen and consulted on hundreds of scleroderma patients during his career. *Id.* at 1. He has over 100 peer-reviewed publications and over 50 invited articles or book chapters. *Id*. at 1–2.

Respondent offered Dr. Oddis as an expert in clinical immunology, rheumatology, and the treatment and diagnosis of scleroderma. Tr. 146:15–18. Petitioner did not object. Tr. 146:19–21.

B. Expert Reports and Testimony

1. Dr. Byers

It is Dr. Byers's opinion, to a reasonable degree of medical certainty, that the vaccination "caused or substantially contributed to the onset of [Petitioner's] autoimmune disorder." Pet'r's Ex. 20 at 7. Although her overall opinion never wavered, Dr. Byers's supporting rationale evolved throughout the course of this case. In her first report, dated August 24, 2016, Dr. Byers described Petitioner as "a complicated case, which is not unusual in autoimmune diseases like MCTD or scleroderma." *Id.* at 5. Dr. Byers stated that it was clear that Petitioner had an autoimmune disease based on poor esophageal motility, SCL-70 antibody, polyarthralgias, and fatigue. *Id*. However, Dr. Byers felt the safest diagnosis to make at the time was MCTD rather than scleroderma. *Id*. Dr. Byers described a puzzling lack of skin involvement and noted that no rheumatologist had diagnosed Petitioner with scleroderma although there was some mention of the diagnosis in the medical records. *Id*. at 5–6. She noted that Petitioner had Raynaud's but mentioned that carpal tunnel syndrome can also cause that condition. *Id*.

Dr. Byers stated that she arrived at this opinion because Petitioner had a genetic propensity to autoimmune disorders (based on family history), combined with a "temporal association" of symptoms of autoimmune disease appearing three days after vaccination. Pet'r's Ex. 20 at 6-7. She further wrote that the "association between Hepatitis B vaccination and connective tissue disease is supported by the literature[,]"[32] and that there are "18 reports in the VAERS[33] data base

[32] Michael A. Mancano, *ISMP Adverse Drug Reactions* 49(3) Hospital Pharmacy 227-231 (2014); Vincenzo Bruzzese et al., *Connective Tissue Disease Following Hepatitis B Vaccination* 19(5) J. CLINICAL RHEUMATOL. 280-81 (2013).

[33] VAERS, the Vaccine Adverse Event Reporting System, is "a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). . . . VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. VAERS is not designed to determine if a vaccine caused a health problem but is especially

associating Hepatitis B vaccination with mixed connective tissue disease." *Id*. at 7. Dr. Byers explained that, in her opinion, the "mechanism of action [is] probably due to activation of T cells and/or antibodies present from her earlier vaccination which release[d] cytokines that are capable of activating autoreactive T cells."[34] *Id*.

Dr. Byers submitted a second report almost a year later in response to concerns raised in Dr. Oddis's first report. Pet'r's Ex. 25. First, Dr. Byers noted Dr. Hinchcliff's diagnosis of connective tissue disease versus sine scleroderma (the latter which does not usually involve skin manifestations). Pet'r's Ex. 25 at 1–2. Second, Dr. Byers stated that although Petitioner had Raynaud's syndrome and was thus at risk of developing an autoimmune disorder, "many people with Raynaud's, perhaps a majority, never develop any form of autoimmune disorder." Pet'r's Ex. 25 at 2. Dr. Byers agreed with Dr. Oddis that three weeks between vaccination and the abnormal esophageal motility test is too short to develop diffuse scarring associated with scleroderma. *Id*. However, Dr. Byers asserted that "scarring is preceded by inflammation which causes the same symptoms, and the time period is correct for development of inflammation associated with the onset of [Petitioner's] autoimmune disease process after vaccination." *Id*. Dr. Byers also agreed that a positive ANA is characteristic of connective tissue disease, but not all cases have it. *Id*. Finally, Dr. Byers concluded that although Petitioner's condition "does not fall into the precise 'pigeon hole' that most rheumatologists, including Dr. Oddis, would prefer," Petitioner "has an autoimmune disease [similar to] connective tissue disease/sine scleroderma, and it was caused or contributed to by the vaccinations she received [in] June 2013." *Id*. at 2.

At the entitlement hearing, Dr. Byers began by defining general concepts. She explained that "[m]ixed connective tissue disease is one of the four categories of rheumatologic diseases that falls under the umbrella of overlap syndromes." Tr. 78:16–18. She then identified four additional diseases that fall under that umbrella: "systemic lupus erythematosus, polymyositis, scleroderma, and rheumatoid arthritis." Tr. 78:18–20. These four diseases are called "overlap syndromes", because they do "not declare themselves … for a long time."[35] Tr. 78:20–22. She went on, "[m]ixed connective tissue disease is arthralgias, arthritis" and "can have a strong component of esophageal dysmotility." Tr. 79:3–5. MCTD can look very similar to other autoimmune diseases and is associated with "anti-RNP[36] antibodies and also with ANA antinuclear antibodies with a speckled pattern." Tr. 79:7–13. An autoimmune disorder is when the body's immune system "react[s] against self-proteins and causes damage." Tr. 79:17–22. She continued, "[i]n scleroderma the fibroblasts secrete collagen and the collagen kind of holds us all together. And it's thought or at least was thought recently that there [are] cytotoxic T cells that are directed

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useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine." *About VAERS*, VAERS, https://vaers.hhs.gov/index.html (last visited Aug. 18, 2020).

[34] Agmon-Levin, N. et al., *Vaccines and Autoimmunity,* NAT. REV. RHEUMATOL. (2009) 5:648-652.

[35] Upon my questioning later in the hearing, Dr. Byers attempted to clarify these categories and primarily confirmed that autoimmune conditions are difficult to diagnose due to overlapping symptoms. Tr. 131-133.

[36] RNP is an abbreviation for ribonucleoprotein and is "a complex of protein and ribonucleic acid." *Ribonucleoprotein*, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=43852 (last visited Aug. 18, 2020).

against the fibroblasts. And they release the collagen and then the collagen causes scarring in both the skin and the internal organs." Tr. 80:6–12.

Dr. Byers described two types of scleroderma: systemic (which involves internal organs but primarily presents as lesions on the skin) and sine (which involves internal organs but not the skin). Tr. 81:3–11. Connective tissue disease and scleroderma are both autoimmune disorders, and Dr. Byers noted that quite a few autoimmune diseases closely follow infections. Tr. 82:19–23. Dr. Byers testified that the vaccine community usually considers that if an autoimmune disease "is triggered by an infectious agent, it [is] also triggered by the vaccine for that infectious agent." Tr. 82:23–83:2. She further testified that, in her opinion, hepatitis B vaccine can trigger autoimmune disease process. Tr. 83:3–5. She explained that the hepatitis B vaccination "can trigger demyelinating diseases by a mechanism called molecular mimicry." Tr. 83:6–14. She said she knew of no "cross-reactivity between hepatitis B and either mixed connective tissue disease or scleroderma, but it is accepted by the vaccine community that, in fact, it can do the same thing by something called bystander activation." Tr. 83:7–14. All vaccines release cytokines and "[b]ystander activation is primarily a cytokine dysfunction in which the vaccination triggers autoreactive T cells on the basis of the cytokine release." Tr. 83:15–21. If people have had previous vaccines of the same type, there are "memory cells" or autoreactive T cells that can react much faster if vaccinated again. Tr. 83:18–84:8. If someone has had a hepatitis B vaccine before, Dr. Byers testified that a subsequent vaccine can cause a reaction in about four to seven days. Tr. 84:9–17.

In Petitioner's case, Dr. Byers indicated she did not see any triggers that might cause an immunological response other than the hepatitis B vaccine. Tr. 84:18–24. Dr. Byers thought Petitioner experienced the side effects commonly seen in the days immediately following the vaccination she received on June 27, 2013. Tr. 85:3–16. By July 1, 2013, Petitioner presented with swelling of the hands and feet and was later described by Dr. Fattah as having muscle pain, swollen joints, [and] numbness of the fingers. Tr. 85:10–86:6. Dr. Byers testified that these symptoms presented four days post-vaccination and are within the time window for the vaccination to be the trigger in her case. Tr. 86:7–11. She was uncertain of what the "current rheumatologic community" thinks the mechanism of action is for initiation of scleroderma. Tr. 86:12–22.

Next, Dr. Byers explained that Raynaud's syndrome is a vascular instability associated with autoimmune diseases, particularly rheumatologic ones, that causes hands or feet to get very cold and change color. Tr. 87:2–17. It can be a harbinger of an autoimmune disease, but at least 50 percent of people who have Raynaud's never develop an autoimmune disease. Tr. 87:12–17. Dr. Byers was not convinced that Petitioner has Raynaud's, because Petitioner denied the color change, and maintained that this diagnosis incorrectly "followed her through the medical records" without confirmation. Tr. 87:21–88:4. Dr. Byers discounted Petitioner's strong family history of rheumatoid arthritis after Petitioner clarified that only a maternal grandmother had the condition. Tr. 88:11–25.

Dr. Byers testified that SCL-70 and ANA tests are both important diagnostics in scleroderma cases. Tr. 89:1–22. SCL-70 is a small, fragile protein, and if it is elevated, it can indicate scleroderma. Tr. 89:6–17. It can also indicate that the serum was damaged through improper handling resulting in a false positive. Tr. 89:11–17. Petitioner, however, has had several

positive SCL-70 tests, which suggests it is not a false positive. Tr. 90:3–10. Dr. Byers noted that Petitioner's several negative ANA tests do not mean she did not have scleroderma. Tr. 90:18–93:10. Dr. Byers testified that by January 18, 2019, Petitioner "developed a positive ANA speckled pattern." Tr. 95:23–96:1.

Dr. Byers asserted that when Petitioner described swollen hands and feet with aches and pain occurring on the Sunday after vaccination, Petitioner was describing arthralgia, which is the early phase of "some kind of rheumatologic autoimmune disease." Tr. 96:2–15. The pain progressed and continued because autoreactive T cells were activated against "various components of the rheumatologic system." Tr. 97:7–13. The symptoms improved with methotrexate, which has been quite successful in several autoimmune diseases. Tr. 97:18–25. This suggests, Dr. Byers contended, that Petitioner's disease is similar. Tr. 97:23–98:1.

Dr. Byers pointed out that Petitioner underwent several gastroenterology tests, which caused the specialist to conclude she had scleroderma with diffuse GI disease, rather than gastric esophageal reflux disease. Tr. 99:3–100:18.

Dr. Byers testified that she agrees with Dr. Hinchcliff's diagnosis of sine scleroderma versus undifferentiated connective tissue disease. Tr. 106:8–17. Dr. Byers thinks Petitioner has either (or both) of these diagnoses and they overlap. Dr. Byers also thinks it is possible that they will overlap for the rest of Petitioner's life without declaring itself. Tr. 106:13–21.

On cross examination, Dr. Byers explained that her opinion that the vaccination caused a reaction within four to seven days assumes that Petitioner had received previous hepatitis vaccines. Tr. 113:17–19. Although Dr. Byers did not have Petitioner's vaccination record, she conceded that the reaction would take longer if it was the first vaccination. Tr. 114:1–9. Assuming Petitioner received previous hepatitis vaccines, Dr. Byers explained that the immune system would activate the cytokines (which cause inflammation) within hours of receiving the vaccination and be symptomatic by "about the fourth day." Tr. 115:1–11. Dr. Byers agreed that one would expect to see some type of damage as a result of inflammation. Tr. 116:1–4.

Dr. Byers testified that inflammation "can morph into the cytotoxic T cells and antibodies" and "[t]he T helper cells will turn on the antibody-forming cells, which then can produce damage by attacking the self-proteins." Tr. 117:11–17. Then she continued, "the cytotoxic cells will cause damage by directly going against the organ and chewing it up." Tr. 117:15–17. She was unsure of how long to expect an inflammatory process to show damage to the tissue it is affecting. Tr. 117:18–20.

ESR, Dr. Byers noted, is used to detect the presence of inflammation caused by infections, tumors, or autoimmune diseases, but Dr. Byers was unsure whether it also measures the degree of inflammation in the body. Tr. 117:21–118:9. She also mentioned the C-reactive protein ("CRP") test as another test used to see whether there is "active and ongoing inflammation." Tr. 118:10–16. Although she agreed that one would expect Petitioner to have markers of inflammation over the last five years, Dr. Byers asserted that sometimes the ESR and CRP tests pick up inflammation, and sometimes they do not. Tr. 118:13–119:6.

Dr. Byers explained that arthralgia and arthritis were used to describe Petitioner's condition. Tr. 119:7–20. It was beyond her expertise to explain whether one could have an arthralgia that is not an arthritis. Tr. 119:21–25. According to Dr. Byers, the first manifestation of Petitioner's autoimmune disease was the swelling in her hands and legs, but the first manifestation of scleroderma was "when she started complaining of difficulty swallowing." Tr. 120:1–14.

Dr. Byers testified that "[r]heumatologic autoimmune diseases in general can be associated with infections or vaccinations," but she was vague on whether there are known causes of scleroderma. Tr. 120:15–23. She agreed there is no medical literature linking vaccinations to scleroderma. Tr. 120:24–121:2. She did not know if the mechanism of injury in rheumatoid arthritis is the same as the mechanism of injury in scleroderma. Tr. 121:5–7. She testified that she reviewed medical literature and databases that showed there is a proximal association between the receipt of the hepatitis B vaccination and mixed connective tissue disease but no determination that the hepatitis B vaccine causes mixed connective tissue disease. Tr. 122:3–12.

When asked about the 18 VAERS reports that she referenced in her first report, Dr. Byers agreed that it is a passive reporting system that does not attribute causality in any case. Tr. 126:11–13. Rather, it just reports a suspicion and one would need to do a randomized clinical trial to prove causation. Tr. 126:11–19. Dr. Byers explained that the VAERS system is intended to serve as a warning system to pharmaceutical companies and regulatory agencies that there may be a problem that should be further researched. Tr. 127:1–4.

Dr. Byers clarified that her indication in her first report that Petitioner had a "clear genetic propensity to an autoimmune disease[,]" was based on medical records that she has since realized were incorrect after interviewing Petitioner. Tr. 129:6–21. She also addressed the issue of whether Petitioner has Raynaud's saying that instead "[s]he just had swelling. And, it's possible that the swelling caused a decrease in the vascularity of the swollen limbs, which could have appeared gray." Tr. 136:11–137:9. Dr. Byers was unable to explain the difference between primary Raynaud's and secondary Raynaud's. Tr. 124:5–7.

Dr. Byers testified that when a vaccine is given, there is an immunological response within hours. Tr. 140:11–19. This response is the innate immune system producing a variety of cytokines. Tr. 140:20–23. She testified that everyone gets some reactions to vaccines, but cytokines are going to be activating the adaptive immune system. Tr. 141:8–18. The resulting symptoms can be either the activation of the adaptive immune system or the innate immune system. Tr. 141:15–18. Petitioner was complaining of significant hand and foot pain on Sunday following the vaccination. Tr. 141:2–25. Dr. Byers testified that it could be either the adaptive or innate immune system, but it would be the vaccine that caused it. Tr. 141:19–142:6.

2. Dr. Oddis

Dr. Oddis submitted a report dated November 17, 2016. Resp't's Ex. A. He disagreed that Petitioner met the criteria for scleroderma, or for any autoimmune disorder, and he opined that her chronic pain is likely related to her established diagnosis of PTSD. *Id.* at 7. He pointed out that Petitioner had a history of Raynaud's phenomenon, musculoskeletal pain, and PTSD before the

vaccination. He noted that her gastrointestinal symptoms, later considered by her doctors to be scleroderma-related, began only three weeks after the vaccination. *Id*. at 4–5. Dr. Oddis further noted that Petitioner never developed skin changes associated with scleroderma, she has no pulmonary involvement, and there is no documented inflammation of her joints. *Id*. at 4. Additionally, Petitioner's gastrointestinal symptoms can all be explained by her pre-existing GERD or her chronic narcotic use. *Id*. Finally, regarding Petitioner's lab reports, Dr. Oddis emphasized that "[i]t is essentially impossible for the ANA to be negative in the setting of a positive anti-SCL-70 autoantibody!" *Id*. at 4. Therefore, he concluded that Petitioner's positive SCL-70 test was a false positive. *Id*. at 5.

On July 28, 2017, Dr. Oddis reviewed Petitioner's updated medical records and authored a supplemental report. Resp't's Ex. C. He noted that Dr. Hinchcliff reviewed the signs and symptoms of scleroderma and found that, of the listed symptoms, Petitioner only had Raynaud's. *Id*. at 2. Dr. Oddis wrote that Petitioner's "primary rheumatic disease manifestations, Raynaud's phenomenon and GERD, predated the hepatitis vaccine." *Id.* He continued that "the gastroparesis noted to be secondary to scleroderma was likely related to chronic narcotic administration, which [Petitioner] continues to take." *Id*. He concluded that Petitioner meets no criteria for an autoimmune disease and in his opinion, the hepatitis vaccination she received in no way contributed to any of her subsequent medical problems. *Id*. at 3.

Dr. Oddis considered Petitioner's diagnosis again in 2019 and provided a third report. Resp't's Ex. E. Even though Petitioner received a laboratory finding that showed a positive ANA test, his opinion that Petitioner does not have scleroderma remained unchanged. *Id*. at 1. In support of his opinion, he noted that the SCL-70 test is "primarily associated with diffuse scleroderma, which [Petitioner] clearly does not have[,]" and she continues to "manifest no overt features of systemic sclerosis (i.e. scleroderma)." *Id*. He stated that it was still his opinion that "the medical evidence in this case fails to show [Petitioner] suffered a vaccine-induced autoimmune disorder" for several reasons. *Id*. at 1–2. First, the initial manifestation of an autoimmune condition was Raynaud's phenomenon, and it preceded the vaccination by at least five years. *Id*. at 2. Next, Petitioner never developed any additional objective manifestations of scleroderma including joint inflammation (all tests of inflammation markers have been normal), scleroderma lung, cardiac, or renal features. *Id*. Petitioner's symptoms of joint and musculoskeletal pain also predated the vaccination and are not features of scleroderma. *Id*. Lastly her esophageal symptoms are non-specific and could be attributable to other causes. *Id*.

At the entitlement hearing, Dr. Oddis provided an overview of autoimmunity by comparing it to a church with pews marked "rheumatoid arthritis," "scleroderma," "polymyositis," or "multiple sclerosis." Tr. 147:18–148:3. Patients sitting in these different pews have laboratory tests that show where they should sit in the "church of autoimmunity." Tr. 148:1–7. Patients with overlap syndrome cannot find the appropriate pew because they have features of more than one autoimmune disease. Tr. 148:8–12. Dr. Oddis continued explaining that there is another distinct pew in the church labeled, MCTD. Tr. 148:13-17. There are four diseases that are part of MCTD: polymyositis, rheumatoid arthritis, systemic lupus, and scleroderma. Tr. 148:20–25. Patients with MCTD may have more symptoms of one disease than another[,] but what they all have is a positive ANA that is "high titer speckled pattern[,]" because that is how MCTD is classified. Tr. at 149:1–6. Dr. Oddis does not think that Petitioner meets the criteria for MCTD. Tr. 150:3–16. The most

recent ANA test in 2019 was positive, but it was not a high titer in a speckled pattern. Tr. 150:9–16.

Dr. Oddis testified that the combination of a positive SCL-70 and a negative ANA does not exist and is a red flag in diagnosing scleroderma. Tr. 151:15–152:11. However, he then stated that 96 percent to 99 percent of patients have positive results for both tests. Tr. 151:15–152:11. Dr. Oddis defined sine scleroderma as scleroderma without skin manifestations such as sclerodactyly, which is thickening of the fingers, hands, and toes. Tr. 154:11–20. He then questioned Petitioner's diagnosis of sine scleroderma by explaining internal manifestations that Petitioner does not have, including fibrosis of the lung, renal crisis, or inflammatory joint pain. Tr. 156:17–157:10. He reviewed Petitioner's gastrointestinal condition noting that symptoms were reported within three weeks of the vaccination but appeared to have started prior to the vaccination. Furthermore, these symptoms never advanced to pseudo-obstruction or gastric antral vascular ectasia, two scleroderma related GI conditions. Tr. 157:11–158:12.

Dr. Oddis testified that although Petitioner claimed her hands and feet were swollen, he reviewed all her records and did not see any clinical notes that described objective evidence of swollen joints. Tr. 159:1–160:3. Dr. Oddis described rheumatoid arthritis as "the prototypical arthritis in autoimmunity." Tr. 160:12–18. He explained that arthritis is an inflammatory condition and a patient with rheumatoid arthritis over time would have joint destruction if left untreated. Tr. 160:12–18. He stated that the erythrocyte sedimentation rate and the C-reactive protein are common tests to identify inflammation, and Petitioner's tests from 2013 to 2019 did not show either to be elevated. Tr. 160:22–161:12.

Dr. Oddis next turned to Dr. Byers's opinion that the vaccination injured Petitioner through the process of bystander activation. Dr. Oddis agreed that "T cells are part of the immune system and whenever they are activated, they release cytokines." Tr. 163:1–6. Cytokines are inflammatory mediators and are capable of bringing in other types of inflammatory cells creating a "cascade of inflammation that occurs whenever an inflammatory process is initiated and perpetuated." Tr. 163:1–24. If such a process happened in Petitioner, Dr. Oddis testified he would expect to see objective evidence in the medical records of elevated inflammatory markers in the blood or confirmation by a physician's examination that there was swelling, thus indicating inflammation in the joints. Tr. 164:10–23. He did not see laboratory tests or physical examinations that showed such a process. Tr. 164:10–23.

Dr. Oddis disagreed with Dr. Byers's conclusion that Petitioner's "clinical course went significantly downhill after receipt of her June 27, 2013 vaccination." Tr. 166:13–23. Dr. Oddis testified that he would expect to see not just skin changes, but also other organ manifestations such as lung, kidney, and heart, and he did not see a progressive accumulation of symptoms in the medical record. Tr. 168:2–9. He discussed Petitioner's GI complaints in more detail. When Petitioner saw Dr. Mughni, he noted Petitioner's complaints of constipation and acid reflux approximately three weeks after the vaccination. Tr. 169:9–170:6. Dr. Oddis stated that if these symptoms of bowel and esophageal involvement are early signs of scleroderma, there is no way to relate them to the vaccination because scleroderma scarring could not occur so quickly. Tr. 170:7–24. It would also be unlikely that a scleroderma patient would experience inflammation in

just the esophagus without objective evidence of inflammation in other tissues such as the skin or the joints. Tr. 172:19–173:16.

Dr. Oddis testified that it is possible that fibromyalgia could have caused the joint pain Petitioner was complaining of during the period after the vaccination. Tr. 173:17–174:12. Petitioner was diagnosed with fibromyalgia, and Dr. Beyley confirmed she had 18 tender points. Tr. 174:21–176:10. Dr. Oddis testified he knows of no evidence showing the hepatitis vaccine causes fibromyalgia. Tr. 177:11–13. Petitioner also complained of muscle weakness but subsequent EMGs and a muscle biopsy were all normal. Tr. 177:14–178:11.

During cross examination, Dr. Oddis agreed that autoimmune diseases can be triggered but did not know of any evidence that they could be triggered by vaccination. Tr. 190:15–23. Dr. Oddis defined a trigger as an immune response activator that cascades into the disease. Tr. 191:18–25. He could not say the length of time between the trigger and the manifestation of an autoimmune disease, because it varies depending on the patient. Tr. 192:1–25. He testified that the medical community still does not know what the trigger is for lupus, rheumatoid arthritis, scleroderma, or myositis. Tr. 193:5–17. Dr. Oddis stated that, without more data, he did not have an opinion on the immunologic concept of bystander activation. Tr. 206:1–9. He did not discount the possibility that a vaccine could trigger a disease that had already started, but he would need to see objective evidence of inflammation. Tr. 207:15–208:18.

Later, upon further questioning from Respondent's counsel, Dr. Oddis reviewed the July 1, 2013 note written by the first doctor to examine Petitioner after the vaccination. Tr. 211:21–212:9. The note was made four days after vaccination, and Dr. Oddis testified that the doctor indicated normal range of motion, normal strength, and no swelling. Tr. 212:3–21. Dr. Oddis explained that a doctor can detect swelling, because it feels "mushy." Tr. 212:12–213:6. This is called synovitis or inflammation. Tr. 213:1–6. Finally, Dr. Oddis explained that fibromyalgia complicates the treatment of even well-documented autoimmune diseases, since a patient can have both. Tr. 219:4–221:21.

IV. Applicable Legal Standard

To receive compensation under the Vaccine Act, Petitioner must demonstrate either that: (1) she suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to the vaccine in question within the time frame prescribed by the Vaccine Injury Table set forth at § 14, as amended by 42 C.F.R. § 100.3; or (2) that her illness is an "off-Table Injury," one not listed on the Table, that resulted from her receipt of a covered vaccine. *See* § 11(c)(1)(C); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner does not assert a Table claim. Thus, she must prove that her vaccine was the cause-in-fact of her injury.

To establish causation-in-fact, Petitioner must demonstrate by a preponderance of the evidence that the vaccines were the cause of her injury. § 13(a)(1)(A). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the

judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner must demonstrate that the vaccine was "'not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)). The vaccine received, however, need not be the predominant cause of the injury. *Shyface*, 165 F.3d at 1351.

A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1). In *Althen v. Sec'y of Health & Human Servs.*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278 (Fed. Cir. 2005). The *Althen* test requires a petitioner to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.* (internal citations omitted).

Specifically, under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question "can [the] vaccine(s) at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). This may be accomplished in a number of ways. "Reliability and plausibility of . . . pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory, so as to render it credible." *Id.* Additionally, "epidemiological studies and an expert's experience, while not dispositive, lend significant credence to the claim of plausibility." *Id.* Medical literature published in respected medical journals is also persuasive. *Id.* "However, publication 'does *not* necessarily correlate with reliability,' because 'in some instances well-grounded but innovative theories will not have been published.'" *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593–94 (1993) (emphasis in original)). Furthermore, a petitioner is not required to present medical literature or epidemiological studies to prove her burden. *Grant v. Sec'y of Health and Human Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992); *Andreu v. Sec'y Health & Human Servs.*, 569 F.3d 1367, 1380 (Fed. Cir. 2009). However, to the extent medical literature and epidemiological studies are provided, these are subject to critique by Respondent's experts, and the special master will consider them when deciding whether the petitioner has met her burden of proof. Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

In addition to showing that the vaccine at issue can cause a particular injury, a petitioner must also, under *Althen's* second prong, prove that the vaccine actually did cause the alleged injury in her particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1278. A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original) (internal citations omitted). Ruling out other potential causes is an important element but does not itself establish causation. *Id.* Additionally, conjecture or speculation does not meet the preponderance standard. *Id.*

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Human Servs.*, 24 Cl. Ct. 400, 403–04 (Fed. Cl. Oct. 23, 1991); *see also Grant*, 956 F.2d at 1148 ("'[T]he inoculation is not the cause of every event that occurs within the ten[-]day period. . . . Without more, this proximate temporal relationship will not support a finding of causation.'" (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))). A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.,* 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

Petitioners who demonstrate by a preponderance of the evidence that they suffered an injury caused by vaccination are entitled to compensation, unless Respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1386 (Fed. Cir. 2015) (citing *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (holding that it is not a petitioner's burden "to rule out possible alternative causes" (internal citations omitted))); *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994).

Respondent frequently offers experts to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (internal citations omitted). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special

masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Both parties filed medical and scientific literature in this case, but not every filed item was probative to the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered").

V. Discussion

A. Petitioner's Diagnosis

Petitioner initially filed her petition with no diagnosed injury, claiming only that the hepatitis vaccine caused her to suffer pain, fatigue, and weakness. She now claims that the hepatitis B component of the vaccine caused her to develop undifferentiated connective tissue disease and sine scleroderma. Respondent, on the other hand, contends Petitioner does not have scleroderma or any other autoimmune disease. Since I cannot determine whether the vaccination caused the Petitioner's injury without first establishing what her injury is, the first step in this case is to determine what injury is best supported by the evidence in the record. *Broekelschen v. Health & Human Serv.*, 618 F.3d at 1346. After a careful review of the record, I find the evidence supports, by a preponderant standard, that Petitioner currently suffers from a condition described by Dr. Hinchcliff as "undifferentiated connective tissue disease versus sine scleroderma."

Dr. Byers accurately noted in her first report that Petitioner presents a complicated case, which is not unusual with autoimmune diseases. Pet'r's Ex. 20 at 5. Generally, when doctors diagnose a disease, the doctor evaluates the patient's signs and symptoms and compares them to the diagnostic criteria. Because the treating doctors have direct experience with the patient whom they are diagnosing, their views about the appropriate diagnosis are often persuasive. *See McCulloch v. Sec'y of Health & Human Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). Unfortunately, in this case, a series of treating doctors, including at least five rheumatologists (who typically diagnose and treat autoimmune diseases), assessed Petitioner with little agreement among them. Similarly, the experts retained in this matter have also come to different conclusions.

In the months and years since vaccination, Petitioner has presented to rheumatologists with complaints of pain and stiffness in her joints and muscles, as well as an assortment of gastrointestinal symptoms, shortness of breath, and dry eyes. Petitioner's first rheumatologist, Dr. Mughni, noted on July 17, 2013, that she had a history of Raynaud's[37] but also that her serologies

[37] As previously noted, Raynaud's phenomenon is considered a harbinger of autoimmune disease, and it is a symptom of scleroderma. Petitioner's history prior to the vaccination is notable for a diagnosis of

were normal. Pet'r's Ex. 3 at 9–12. As a result, he concluded she suffered from fibromyalgia and chronic fatigue syndrome. *Id*. Dr. Rodriguez was the second rheumatologist to consider Petitioner's symptoms. He was the first to record a positive SCL-70, which suggested she had scleroderma, and a negative ANA, which suggested she did not. Pet'r's Ex. 6 at 14–15. He recommended she be evaluated at a specialty center since her diagnosis was unclear. *Id*. Dr. Donohue of the Cleveland Clinic was the third rheumatologist to evaluate Petitioner. He advised her it was possible she had early scleroderma, but ultimately determined that Petitioner's musculoskeletal discomfort was likely myofascial pain. Pet'r's Ex. 16 at 1–7. Dr. Lin was Petitioner's fourth rheumatologist. Pet'r's Ex. 14 at 1–4. He diagnosed systemic scleroderma and treated her with hydroxychloroquine and methotrexate. *See generally* Pet'r's Exs. 19, 22. Dr. Hinchcliff of the Northwestern Scleroderma Clinic is Petitioner's current rheumatologist, and she diagnosed Petitioner with undifferentiated connective tissue disease versus sine scleroderma. In support of Dr. Hinchcliff's diagnosis, Petitioner had laboratory testing performed in January of 2019 that resulted in another finding of positive SCL-70 (again suggesting scleroderma) plus a positive ANA in a speckled pattern (suggesting connective tissue disease).

At the entitlement hearing, both experts discussed the challenges of diagnosing autoimmune diseases. It is often the case that these patients have symptoms of more than one disease, resulting in overlapping conditions and diagnostic uncertainty. When Dr. Byers prepared her first report in connection with this case, she felt Petitioner had an autoimmune disease, but she did not feel comfortable diagnosing Petitioner with scleroderma due to the lack of skin involvement. Pet'r's Ex. 20 at 5. At the hearing, Dr. Byers testified that she agreed with Dr. Hinchcliff that Petitioner had connective tissue disease or sine scleroderma, and furthermore, they overlap and will probably overlap for the rest of Petitioner's life without a clear diagnosis. Tr. 106:10–21.

Dr. Oddis, on the other hand, believes very strongly that Petitioner does not have any form of autoimmune disease, because she never developed skin changes associated with scleroderma, has no pulmonary involvement, and there is no documented inflammation of her joints anywhere in the records. Resp't's Ex. A at 4.

After a thorough review of the medical records, I find it compelling that Dr. Hinchcliff, a treating rheumatologist practicing at the Northwestern Scleroderma Clinic, addressed the overlap in Petitioner's symptoms and diagnosed her with undifferentiated connective tissue disease versus sine scleroderma. Dr. Hinchcliff had the opportunity to examine Petitioner in person on more than one occasion. After a review of Petitioner's history of Raynaud's, lab results, and reports from other specialists, Dr. Hinchcliff concluded that Petitioner has some form of connective tissue disease overlapping with scleroderma. Dr. Lin, the rheumatologist who treated Petitioner immediately prior to Dr. Hinchcliff, also considered Petitioner to suffer from undifferentiated connective tissue disease with possible systemic sclerosis and treated her accordingly. The

Raynaud's, and the diagnosis appears throughout her medical records until at least 2019. Most of the rheumatologists she saw after the vaccination and both experts considered it significant in evaluating her for an appropriate diagnosis, although Dr. Byers now maintains that Petitioner does not have Raynaud's.

diagnosis appears to be confirmed by the most recent laboratory results showing positive SCL-70 and positive ANA.

Although this is a close call, petitioners are accorded the benefit of close calls in the Vaccine Program. *Knudsen v. Health & Human Serv,* 35 F.3d at 549. Therefore, I find that Petitioner has provided preponderant evidence that she suffers from undifferentiated connective tissue disease versus sine scleroderma.

B. *Althen* Prong One

Petitioner's general theory, as explained by Dr. Byers, is that the hepatitis vaccine, like all vaccines, can trigger autoimmune diseases through a process called bystander activation. Undifferentiated connective tissue disease and sine scleroderma are both autoimmune diseases, therefore, it is Dr. Byers's opinion that the hepatitis vaccine can trigger them. Dr. Byers provides little detail of the mechanism by which the hepatitis vaccine could trigger bystander activation to cause either connective tissue disease or scleroderma. She testified that all vaccines release cytokines, and bystander activation is a cytokine dysfunction where the vaccination triggers autoreactive T cells through cytokine release. Tr. 83:15–84:8. Dr. Byers described this same process in her first report and referenced an article[38] from 2009 that asserts that vaccines can trigger an immune response that might eventually lead to an autoimmune disorder. Pet'r's Ex. 20, 28. Although the article mentions an association between the hepatitis B vaccine, multiple sclerosis, and acute central nervous system inflammatory demyelination, there is no mention of connective tissue disease or scleroderma.

At the entitlement hearing, Dr. Byers first testified that the hepatitis B vaccination can trigger demyelinating diseases by a mechanism called molecular mimicry. Tr. 83:3–14. However, she could not describe what would lead to cross-reactivity between hepatitis B and either mixed connective tissue disease or scleroderma. Tr. 83:3–14. Consequently, Dr. Byers moved on to the bystander activation theory, because "it is accepted by the vaccine community that, in fact, it can do the same thing[]." Tr. 83:3–14.

Dr. Byers asserted at the hearing that rheumatologic autoimmune diseases in general can be associated with infections or vaccinations. Tr. 120:15–19. However, she conceded that she was uncertain of the mechanism of injury in scleroderma and unaware of any specific known causes of scleroderma other than some drugs that she could not name. Tr. 120:20–23. Dr. Byers was unable to find any medical literature linking the hepatitis vaccine, or any vaccines, to scleroderma. Tr. 120:24–121:4. When she referred instead to literature linking vaccinations to rheumatoid arthritis, she was unable to explain whether the mechanism of injury was the same with scleroderma as with rheumatoid arthritis, and if so, how. Tr. 121:2–7.

Dr. Byers testified that a proximal relationship between the hepatitis B vaccine and mixed connective tissue disease had been reported but she could not recall the details without reviewing the literature. She referenced two case studies[39] in her first report to show connective tissue disease following the hepatitis B vaccination. Pet'r's Exs. 29, 30. However, upon closer look, they appear

[38] Agmon-Levin, *supra* note 34.
[39] See e.g., *supra* note 32.

to be two accounts of the same 43-year-old woman with no history of autoimmune disease who developed symptoms of undifferentiated connective tissue disease after receiving the vaccination. Neither report determined that the hepatitis B vaccine was the cause of the disease or explained the mechanism by which the vaccination led to the development of the disease. Dr. Byers also mentioned 18 reports in the VAERS database associating hepatitis B vaccine and mixed connective tissue disease but agreed at the hearing that VAERS is a passive reporting system and does not attribute causality in any of the cases. Pet'r's Ex. 20 at 7, Tr. 126:3–21.

While Dr. Oddis thoroughly explained his opinion that Petitioner does not have scleroderma, he did not have much to add regarding whether the hepatitis vaccination can cause autoimmune disease. He testified that when T cells are activated, they release cytokines as part of the adaptive immune system and the cytokines bring in other types of inflammatory cells, leading to a cascade of inflammation. Tr. 162:8–163:24. However, he clarified that immunologic activation is the result of a trigger, such as infection, and not the cause of it. He then questioned whether a specific trigger can be identified in the development of autoimmune diseases. Tr. 190:24–193:17. He also questioned whether there is enough data to confirm the bystander hypothesis, but he did not rule out the possibility that a vaccine can trigger illness. Tr. 206:1–17.

Although both parties were vague in their efforts to address prong one in this case, the burden is on Petitioner to make a case. Bystander activation is a not a novel theory of autoimmunity. See e.g., *Bender v. Sec'y of Health & Human Servs.,* No. 11-693V, 2018 WL 3679637 (Fed. Cl. July 2, 2018), *review den'd*, 141 Fed. Cl. 262 (2019); *see also Bucci v. Sec'y of Health & Human Servs.,* No. 11-513V, 2019 WL 1891809 (Fed. Cl. Mar. 27, 2019). However, the ability of vaccines generally to stimulate the immune system does not establish a pathogenic effect. Furthermore, simply because other vaccines can cause autoimmune disease is not enough to prove that a hepatitis vaccine can cause either sine scleroderma or connective tissue disease. Accordingly, I have concluded that the evidence of bystander activation is too speculative to establish a theory of vaccine causation in this case. Therefore, Petitioner has not carried her burden to establish by a preponderance of the evidence that bystander activation is a theory under which the hepatitis vaccine can cause undifferentiated connective tissue disease or sine scleroderma.

C. *Althen* Prong Two

Petitioner relies primarily on the timing of symptom onset and the lack of other triggers to show that the hepatitis vaccine caused her illness.[40] She claims that she was healthy and very active prior to the vaccination and then developed symptoms of a connective tissue disease by the fourth day post vaccination. Petitioner asserts in her post hearing brief that her records provide a straight line between the vaccination on June 27, 2013, and her current diagnoses of undifferentiated connective tissue disease and sine scleroderma. This claim, however, ignores the medical records immediately prior to the vaccination (specifically the references to Raynaud's), which tend to suggest that Petitioner's symptoms began before she was vaccinated. Pet'r's Ex. 1 at 1–5.

[40] Dr. Byers also cited to Petitioner's "clear genetic propensity to autoimmune disease" in her first report as a basis for her opinion that the vaccination contributed to the onset of the autoimmune disorder but changed her mind at the hearing after speaking with Petitioner about her family medical history. Pet'r's Ex. 20, Tr. 128.

Petitioner testified that Dr. Lyon initially diagnosed her with Raynaud's phenomenon after he observed her feet were gray, and she told him they change color and feel cold at times. Tr. 18:1–11. Presumably, this is the visit in April of 2013, when he assessed her with Raynaud's and vasomotor instability. Pet'r's Ex. 1 at 1–5. Dr. Byers testified that Raynaud's is often a harbinger of autoimmune disease and that 90 percent of scleroderma patients have it. Each of Petitioner's rheumatologists noted her Raynaud's diagnosis, including Dr. Hinchcliff who wrote that Petitioner's Raynaud's began in 2008. This strongly suggests that Petitioner's disease process was already underway when she was vaccinated in 2013.

Dr. Byers mentioned Petitioner's pre-existing Raynaud's in her first report but questioned whether she had been tested for it. Pet'r's Ex. 20 at 5. Dr. Byers also noted that Petitioner's carpel tunnel syndrome can cause Raynaud's. *Id.* In her second report and at the entitlement hearing, Dr. Byers asserted that many people with Raynaud's never go on to develop scleroderma or other autoimmune diseases. This assertion belies the facts in this case where Petitioner did develop scleroderma. Dr. Byers went further at the entitlement hearing insisting that, despite the agreement of the rheumatologists who examined and treated Petitioner, Petitioner did not have Raynaud's. This opinion was based on a conversation Dr. Byers had with Petitioner the night before the hearing. Dr. Byers theorized that Petitioner could have had swelling in her lower extremities that caused her skin to appear gray to Dr. Lyon. Tr. 136:11–137:9.

Although Dr. Byers deferred to and agreed with Dr. Hinchcliff in the diagnosis of Petitioners undifferentiated connective tissue disease and sine scleroderma, Dr. Byers disregarded Dr. Hinchcliff's diagnosis of Raynaud's. However, as Dr. Byers noted, Dr. Hinchcliff is a board-certified rheumatologist and the associate clinical director for the Northwestern Scleroderma Clinic. Whereas, Dr. Byers has no specialized rheumatological training other than her residency for internal medicine and a three-year fellowship many years ago. Tr. 75:8–18. As previously mentioned, Petitioner agreed at the entitlement hearing that while Dr. Byers was qualified to read and interpret what treating doctors have done, she is not qualified to make any separate rheumatological diagnoses as part of her testimony. Tr. 78:1–7. The treating providers unanimously concluded that Petitioner has Raynaud's, and it appears to have manifested prior to the vaccination at issue in this case. The straight line seems to be between the appearance of Raynaud's in April of 2013, and the current diagnoses of undifferentiated connective tissue disease and sine scleroderma. *See Locane v. Sec'y of Health & Human Servs.,* 99 Fed. Cl. 715, 729 (2011), *aff'd,* 685 F.3d 1375 (Fed. Cir. 2012) (holding "[n]owhere in the statutory scheme of Federal Circuit precedent emerges a requirement that the special master conduct a causation analysis once the special master has determined that a preponderance of the evidence shows that the onset of the illness predates the vaccination").

Notwithstanding Petitioner's pre-existing Raynaud's, Petitioner's timeline is not compelling. Dr. Byers based her opinion that the hepatitis vaccine triggered Petitioner's autoimmune disease on Petitioner's complaint of swelling in her hands and feet four days post vaccination. Tr. 109:7–110:24. If Dr. Byers is correct that Petitioner had swelling in her feet rather than Raynaud's prior to the vaccination, then it seems her autoimmune symptoms started before the vaccination and were not triggered by it. Furthermore, the medical records from the month immediately after the vaccination are significant for complaints of joint pain with no objective documentation of joint swelling.

Dr. Oddis suggested in his testimony that Petitioner's complaints of joint pain during the post-vaccination period are better explained by fibromyalgia, for which Petitioner was diagnosed and treated by her first rheumatologist. Tr. 173:17–174:12, Pet'r's Ex. 3 at 9–12. The first objective indication that Petitioner might have an autoimmune disease rather than fibromyalgia was not until March of 2014 when she tested positive for SCL-70 antibodies. Her diagnosis remained uncertain for years after that due, in part, to her consistently negative ANA. It is possible that Petitioner had ongoing fibromyalgia that accounted for her joint pain in 2013 and, as Dr. Oddis testified, fibromyalgia complicates the treatment of even well-documented autoimmune diseases, since a patient can have both. Tr. 219:4–221:21.

Although I determined that Petitioner provided preponderant evidence that she now has undifferentiated connective tissue disease versus sine scleroderma, the record is unclear when she developed the disease and unclear what triggered it. Respondent argued that Dr. Byers' theory of vaccine causation depends on the existence of an inflammatory process upon receipt of a vaccination, but there is no evidence of such a process. Resp't's Post-Hr'g Br. at 15. Indeed, there are no objective indicators that Petitioner experienced inflammation in the period immediately following the vaccination that would suggest an inflammatory process was taking place. Dr. Byers testified that scleroderma is an inflammatory disease and, based on the bystander activation mechanism of injury, she would have expected to see markers of inflammation in Petitioner. She conceded that there were none. Tr. 117:1–119:6. It is undisputed that there were no markers of autoimmune disease in temporal connection to Petitioner's vaccination, thus casting doubt on bystander activation as the cause of Petitioner's disease.

Dr. Byers failed to articulate "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. Accordingly, based on the forgoing, I find that Petitioner has failed to show by preponderant evidence that the hepatitis vaccine was the cause of her claimed condition.

D. *Althen* Prong Three

Dr. Byers proposed a timeline for disease onset of four to seven days post-vaccination since, according to Petitioner's testimony, she had previously been exposed to the hepatitis B vaccine. Tr. 84:9–17, 113:17–115:17. Dr. Byers agreed that the timeline would be longer if this was Petitioner's first hepatitis B vaccine. Tr. 113:17–115:17. As with the first and second prongs, Dr. Byers supports her opinion regarding onset with general assertions about vaccines causing autoimmune diseases by way of bystander activation. She provides no basis for her opinion that a hepatitis B vaccine causes onset of either connective tissue disease or scleroderma in four to seven days post-vaccination. Dr. Byers also disregards Petitioner's account of symptoms during the first few days after vaccination as general malaise from "normal side effects from a vaccination." Tr. 85:6–16. Dr. Byers was uncertain whether it was the adaptive or innate immune system causing Petitioner's hand and foot symptoms during the initial week, concluding simply and vaguely that it was the vaccine that caused them. Tr. 140:11–142:6. Petitioner has not provided preponderant evidence that four to seven days is an appropriate temporal relationship for hepatitis B vaccine induced undifferentiated connective tissue disease verses sine scleroderma.

VI. Conclusion

After a review of the record, including Petitioner's medical records, expert reports, accompanying literature, and testimony, Petitioner has not proven it is more likely than not that she suffered from a vaccine-caused injury.

Accordingly, I have no choice but to DENY Petitioner's claim and DISMISS this petition.[41]

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

[41] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.